§5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the assigned functions of the respective Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Premarket Approval, CFSAN.

(iv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all of the functions of the Commissioner of Food and Drugs under sections 409 and 721 of the act regarding the approval of the use of food additives under section 409(e) of the act and the listing of color additives under section 721(d) of the act where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of notices of temporary permits for foods varying from standards of identity under §130.17 of this chapter:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner of Food and Drugs regarding approvals of the use of food additives under section 409(e) of the act, where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act or to color additive petitions under section 721(d)(1) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Premarket Approval, CFSAN.

(iv) The Director, Division of Product Policy, Office of Premarket Approval, CFSAN.

(v) The Director, Division of Petition Control, Office of Premarket Approval, CFSAN.

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 721 of the act:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Cosmetics and Colors, CFSAN.

(e) The following officials are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under § 130.6 of this chapter:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming generally recognized as safe (GRAS) status of food substances under § 170.35 or § 570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director and Deputy Director, CVM.

(g)(1) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuance of decisions to grant or deny petitions for nutrient content claims and health claims that do not present controversial issues and regarding the issuance of any notices of proposed rulemaking that result from such action:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the ''threshold of regulation'' under § 170.39 of this chapter:

(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

(i) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409(h) of the act, excluding the duties set out in section 409(h)(5) of the act, regarding premarket notification of food-contact substances:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Regulations and Policy, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

[49 FR 14936, Apr. 16, 1984, as amended at 49 FR 48183, Dec. 11, 1984; 52 FR 5951, Feb. 27, 1987; 58 FR 2410, Jan. 6, 1993; 59 FR 42492, Aug. 18, 1994; 60 FR 36594, July 17, 1995; 64 FR 33194, June 22, 1999]

§ 5.62 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under § 108.5 of this chapter.